UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOGEN IDEC, INC. SECURITIES LITIGATION	:	Civil Action No. 05-10400-RCL

ASSENTED-TO MOTION FOR LEAVE TO SUBMIT SUPPLEMENTAL AUTHORITY IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

Defendants Biogen Idec, Inc. ("Biogen Idec"), James C. Mullen, Burt A. Adelman, Peter N. Kellogg, William H. Rastetter and William Rohn (collectively with Biogen Idec, "Defendants"), respectfully submit this motion pursuant to Local Rule 7.1(B)(3) for leave to submit a recent District of Massachusetts decision in connection with the Court's consideration of their motion to dismiss, filed November 15, 2006 (Docket No. 82) and argued March 12, 2007.

Defendants respectfully request that the Court consider Judge O'Toole's March 28, 2007 decision dismissing with prejudice claims arising out of alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (15 U.S.C. § 78a et seq.). In re Praecis Pharm., Inc. Sec. Litig., Civ. A. No. 04-12581-GAO (D. Mass. Mar. 28, 2007). A copy of Judge O'Toole's Memorandum And Order in In re Praecis Pharm., Inc. is attached hereto as Exhibit A.

Dated: April 5, 2007
Boston, Massachusetts

Respectfully submitted,

/s/ James R. Carroll

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LOCAL RULE 7.1 CERTIFICATION

I, Michael S. Hines, hereby certify that, in compliance with Local Rule 7.1(A)(2), I conferred with counsel for Plaintiffs and counsel for defendant Thomas Bucknum and they assent to the relief sought by this motion.

Dated: April 5, 2007

/s/ Michael S. Hines
Michael S. Hines

CERTIFICATE OF SERVICE

I, Michael S. Hines, hereby certify that a true copy of the foregoing document filed through the ECF system will be electronically sent to the registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent to those indicated as non-registered participants on April 5, 2007.

Dated: April 5, 2007

/s/ Michael S. Hines
Michael S. Hines

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 04-12581-GAO

IN RE: PRAECIS PHARMACEUTICALS, INC. SECURITIES LITIGATION

MEMORANDUM AND ORDER
March 28, 2007

O'TOOLE, D.J.

I. Introduction

This is a putative class action alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 of the Securities and Exchange Commission ("Rule 10b-5m"), 17 C.F.R. 240.10b-5, brought against Praecis Pharmaceuticals, Inc. ("Praecis" or the "Company") and Praecis' employees Malcolm Gefter, Kevin McLaughlin, Edward English and William K. Heiden (the "Individual Defendants"). The plaintiffs purchased or otherwise acquired shares of Praecis stock between November 25, 2003 and December 6, 2004 (the "Class Period"). At the beginning of the Class Period, Praecis securities were selling at $6.87 per share; by the close of business in December 6, 2004, the share price had fallen to $1.60. The plaintiffs allege that the defendants' misrepresentations and material omissions about Praecis' lead product, Plenaxis, artificially inflated the stock's price until the Company's December 6, 2004 disclosure that it was withdrawing all guidance it had issued on Plenaxis sales and revenues and that it planned to relaunch the drug under a new sales model. The Company's announcement caused the stock price, which had already declined substantially during the Class Period, to drop an additional 25.8%. The plaintiffs claim that as a direct result of the defendants' misrepresentations, they suffered financial damages in connection with their purchase and ownership of Praecis securities.

Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b) and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. §§ 78u-4 and 78u-5, the defendants have moved to dismiss the plaintiffs' Consolidated Amended Complaint. For the reasons set forth herein, the motion to dismiss is GRANTED.

II. Summary of Allegations

Praecis is a biopharmaceutical company. On November 25, 2003, the first day of the Class Period, the Company received Food and Drug Administration ("FDA") approval to market its first product, Plenaxis, a drug for the palliative treatment of advanced prostate cancer. The FDA's approval was contingent upon the drug carrying a "black box" warning label, the establishment of a detailed Risk Management Program ("RMP"), and a limitation on the type of patients to whom Plenaxis could be prescribed, specifically the estimated 5-10% of patients who could not tolerate other hormone therapies and who had refused surgical castration.[1] The FDA imposed these restrictions because studies demonstrated that Plenaxis users were at risk of potentially life-threatening allergic reactions, including hypotension accompanied by a loss of consciousness.

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[1]Black box labels are "designed to highlight special problems, particularly those that are serious, and to give health care professionals a clear understanding of a potential medial complication associated with a drug." http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01325.html (last visited March 24, 2007). A black box warning is the most serious FDA warning for prescription medication labels. See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=34 (last visited March 24, 1007).

A Risk Management Program is a "strategic safety program designed to decrease product risk by using one or more interventions or tools beyond the package insert." FDA Concept Paper: Risk Management Programs, http://www.fda.gov/cder/meeting/riskManageII.htm (last visited March 24, 2007). Among the recommended tools are specialized educational materials for doctors and patients and processes or forms to increase compliance with reduced-risk prescribing. See id.

Praecis publicly forecast that the potential market for Plenaxis was $160 million to $360 million. Specifically, in a November 26, 2003 interview on a cable television show, Gefter, the Company's CEO, stated:

> the current market for hormonal therapy is actually $1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug.

Complaint ¶ 109. Approximately two months later, Praecis announced its consolidated financial results for the three months and year ended December 31, 2003. At that time, Gefter discussed the Company's financial guidance for 2004:

> During 2004, the Company forecasts sales of Plenaxis(TM) to range from $10.0 million to $20.0 million and anticipates the ramp-up of revenues to be heavily weighted toward the second half of the year. The Company anticipates updating its financial guidance throughout 2004, as it gains a greater insight into Plenaxis(TM)' revenue trajectory.
>
> With respect to the future prospects for Plenaxis(TM), the market for currently available hormonal therapies to treat prostate cancer is approximately $1.2 billion in the United States. The Company believes that the long-term revenue opportunity for Plenaxis(TM) may represent 15% or more of this market.

Complaint ¶ 114.

Based on these forecasts, Praecis' stock price rose over 14%. Complaint ¶ 3. The plaintiffs further allege that at the time the forecasts were made, the Company had information at its disposal that indicated that the market for the drug was, in reality, substantially smaller.[2]

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[2] In making these allegations the plaintiffs relied on information provided by "Confidential Sources" (principally former Praecis sales representatives). See Complaint ¶¶ 45, 47-50, 53-56, 59-

At the end of 2003 and during the first quarter of 2004, Praecis worked on building its commercial infrastructure to support the launch of Plenaxis, which included hiring and training its sales force. The plaintiffs allege that during these initial training sessions, sales representatives were encouraged to downplay the seriousness of the drug's health risks and use aggressive sales techniques, including suggesting the use of Plenaxis for cases that were too mild to fall within the FDA-approved indications. Praecis began shipping Plenaxis to distributors in January and the sales force thereafter began enrolling physicians and hospital pharmacies in the Plenaxis(TM) User Safety ("PLUS") Program, which was viewed as the first step towards generating prescribers.[3] The sales force was informed that each representative was expected to acquire ten patients between February 2004 and June 2004, a target that the plaintiffs allege was "plainly inconsistent" with the public 2004 sales forecast of $10-20 million. Complaint ¶ 67.

Sales of Plenaxis during the first quarter of 2004 generated approximately $400,000 in revenues. Despite these modest initial results, in April 2004 Praecis indicated that the Company expected to "build sales during the second half of the year as awareness of the product grows," and, presumably on that basis, reaffirmed its sales forecast of $10-20 million for 2004. Complaint ¶¶ 120-121.

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60. According to these sources, the Company knew that the profit margin for urologists using Plenaxis would be too low to generate strong sales, that the need to establish a distribution network for urologists would add significant costs and would add downward pressure on sales, and that the combination of the black box warning label and the FDA-required RMP would have further adverse effects on the sale of Plenaxis.

[3]The PLUS Program appears to be what Praecis called its required RMP.

Sales in the second quarter did not pick up as much as predicted. On May 24, 2004, the Company announced that year-to-date revenues from sales of Plenaxis were $1,056,000 and informed the market that because "the uptake of [Plenaxis] by subscribers . . . has been somewhat slower than forecasted . . . [Praecis] is not in a position at this time to confirm its previously issued sales range forecast for 2004." Def. Ex. 8 at 2. In part, the plaintiffs say that the poor results during the first half of 2004 stemmed from "substantial" returns of Plenaxis and unexpected distributor "charge backs" of 25% of the cost of the drug for each vial returned. Complaint ¶¶ 76,77.

Over the next two quarters, the Company experienced significant attrition of its sales staff and, according to the plaintiffs, began hiring sales representatives that did not have the experience and skills necessary to sell a drug like Plenaxis. In addition, Praecis changed its pricing policy and ended its rebate program, which allegedly caused dissatisfaction among a number of existing customers. Sales during that time continued to be tepid. Nevertheless, when announcing second and third quarter results, the Company emphasized its success in enrolling physicians in the PLUS Program,[4] as well as the increasing number of purchasing physicians and "repeat prescribers." Complaint ¶¶ 129, 132. Praecis also announced that it expected to see "Plenaxis(R) sales continue to build quarter on quarter over the course of the year" and that "[l]onger-term, the Company continue[d] to believe that the revenue opportunity for Plenaxis(R) may represent 15% or more of the $1.2 Billion hormone therapy market for prostate cancer in the United States." Id.

[4]"PLUS" was the Plenaxis User Safety Program. It was viewed as the precursor to physician's actually prescribing the drug. See Complaint ¶ 127.

Finally, on December 6, 2004, Praecis issued a press release announcing that the company had faced many challenges that "had an adverse impact on the uptake of the product in the market;" predicting decreased sales from the third to the fourth quarter; removing Praecis' previous short and long term sales and earning guidance; and indicating that it would not be providing further guidance until a consistent trend for Plenaxis(R) sales emerged. Complaint ¶ 134. The plaintiffs contend that this news "shocked the market" and that, as a result, Praecis' stock price fell 25.8%, or $0.56 per share.

III. Section 10(b) Claims and the Pleading Requirements Imposed by the PSLRA and Rule 9(b)

To state a claim under Section 10(b), a plaintiff must plead: (1) a misrepresentation or omission of material fact; (2) scienter; (3) reliance on the misrepresentation; (4) damage resulting from the misrepresentation; and (5) loss causation. See Dura Pharmaceuticals, Inc. v. Broudo, 125 S.Ct. 1627, 1631 (2005); Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 193 (1st Cir. 2005). A few points deserve emphasis. First, omission of a fact is "material" only if it is "substantially likely that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." In re Cabletron Sys., Inc., 311 F.3d 11, 34 (1st Cir. 2002) (quoting Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)) (internal citations and quotations omitted).

Second, knowing omissions of information, even if material, are not necessarily actionable. See Gross v. Summa Four, Inc., 93 F. 3d 987, 992 (1st Cir. 1996) ("A corporation does not commit securities fraud merely by failing to disclose all nonpublic material information in its possession."). Absent a legal duty to disclose, there is no liability for simple non-disclosure. There is no general

requirement that a publicly-traded company reveal internal information, even if investors might consider such information important to their understanding of the company's financial condition. See id. Neither the Exchange Act nor Rule 10b-5 creates an affirmative duty to disclose. Id.

That said, "[w]hen a corporation *does* make a disclosure--whether it be voluntary or required--there is a duty to make it complete and accurate." Roeder v. Alpha Industries, Inc., 814 F.2d 22 (1st Cir. 1987) (emphasis added). This does not mean that a company that makes a disclosure about one aspect of its business is obliged to reveal other aspects--even if they might seem significant to investor--unless such revelation is necessary to make the initial disclosure complete and not misleading. See Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc) ("This, however, does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise, but means only such others, if any, that are needed so that what was revealed would not be so incomplete as to mislead.") (internal quotations omitted). "Furthermore, the fact that a company has reported accurately about past successes does not by itself burden the company with a duty to inform the market that present circumstances are less positive." Gross, 93 F.3d at 992.

Plaintiffs alleging securities fraud in violation of the Exchange Act and Rule 10b-5 must meet the pleading requirements set forth in the PSLRA, 15 U.S.C. § 78u-4, which are "congruent and consistent" with the First Circuit's pleading standards under Fed. R. Civ. P. 9(b).[5] Greebel v. FTP Software , Inc., 194 F.3d 185, 193 (1st Cir. 1999). The PSLRA requires that the complaint "specify

[5]Federal Rule of Civil Procedure 9(b) requires that in "all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."

each statement [of material fact] alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); see also In re Stone & Webster, Inc., Securities Litigation, 414 F.3d 187, 194 (1st Cir. 2005) (quoting 15 U.S.C. § 78u-4(b)(1)); Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002) (stating the complaint "must specify each allegedly misleading statement or omission including its time, place and content and must provide factual support for the claim that the statements or omissions were fraudulent, that is, facts that show exactly why the statements or omissions were misleading.") (citations and internal quotations omitted).

Furthermore, where the plaintiffs may only recover money damages upon proof that the defendants acted with a particular state of mind, the PSLRA requires that "with respect to each act or omission alleged" the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C § 78u-4(b)(2). As the language of § 78u-4(b)(2) makes clear, Congress has created a heightened standard for determining whether allegations of scienter made in the context of a securities fraud case should survive a motion to dismiss:

> While under Rule 12(b)(6) all inferences must be drawn in plaintiffs' favor, inferences of scienter do not survive if they are merely reasonable, as is true when pleadings for other causes of action are tested by motion to dismiss under Rule 12(b)(6). Rather, inferences of scienter survive a motion to dismiss only if they are both reasonable and "*strong*" inferences.

Greebel, 194 F.3d at 194.

The PSLRA's pleading standard for scienter requires that the plaintiffs plead facts establishing that the defendants had a "mental state embracing intent to deceive, manipulate, or defraud." See Greebel, 194 F.3d at 194 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)) (internal quotations omitted). There is no particular test to determine scienter; rather, the First Circuit has instructed courts to continue using a case by case, fact-specific approach to determine whether a complaint raises the requisite "strong inference."[6] See Aldridge, 284 F.3d at 82 (citing Greebel, 194 F.3d at 196).

In addition to establishing these two pleading requirements, Congress also created a statutory safe harbor for many types of "forward-looking" statements. See 15 U.S.C. § 78u-5. In a general sense, the statements covered by the provision are those that "speak predictively of the future." In re Stone & Webster, 414 F.3d at 195 (citing 15 U.S.C. § 78u-5(i)(1)).[7] Such statements

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[6]For example, "while mere allegations of motive and opportunity alone may be insufficient, together with additional factual support, evidence of motive and opportunity may establish a strong inference of scienter." Aldridge, 284 F.3d at 82.

[7]The complete definition contained in 15 U.S.C. § 78u-5(i)(1) is as follows:

> The term "forward-looking statement" means--
>
> **(A)** a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> **(B)** a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> **(C)** a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> **(D)** any statement of the assumptions underlying or relating to any

are protected if any of three circumstances is met: (1) the forward-looking statement is identified as such and is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement;" (2) the statement is not material; or (3) the plaintiff fails to show that the statement was made with actual knowledge that it was false or misleading. See 15 U.S.C. § 78u-5(c)(1).

IV. Sufficiency of the Allegations of the Complaint

The complaint quotes a number of statements by the defendants that it alleges were materially false and misleading. In most cases, it appears that the allegation is that the statements were misleading not in the information they contained, but in what they omitted. Typically, the sufficiency of such allegations should be analyzed on a statement-by-statement basis. See In re Credit Suisse First Boston Corp., 431 F.3d 36, 49 (1st Cir. 2005). However, some of the statements are naturally considered in conjunction with other related statements, as, for example, when several statements are found in the same document.

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statement described in subparagraph (A), (B), or (C);

(E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or

(F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

A. The November 25, 2003 Press Release

The first three statements alleged to be misleading, identified in ¶¶ 105, 106 and 107 of the Complaint, are excerpts from a Praecis press release distributed on November 25, 2003, the first day of the Class Period. In the release, the Company announced and commented upon the FDA's approval of Plenaxis, noted that the approval was conditioned with marketing restrictions under 21 C.F.R. 314, Subpart H, including the requirement of a user safety program; and described the PLUS Program. It also detailed pharmacology and clinical results for Plenaxis (including description of negative side effects), and otherwise relayed general information about Praecis. See Def. Ex. 1 at pp. 1-6.[8] Notably, the press release also included a statement that it contained forward-looking statements, and listed a number of "factors and uncertainties" that might influence or alter the stated projections. See id. at p. 7.

The plaintiffs quote three portions of the press release and then allege that they were misleading in what they omitted. The first portion described elements of the PLUS Program, including product labeling describing certain risks from Plenaxis, participation agreements to be signed by physicians and hospital pharmacists, a patient information form to be signed by patients, a program for reporting adverse events to the Company and the FDA, and measures to monitor and evaluate the program. See Complaint ¶ 105; Def. Ex. 1 at 2.

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[8]Normally, consideration of documents external to the complaint converts a motion to dismiss into a motion for summary judgment. See Fed.R.Civ.P. 12(b)(6). The courts recognize narrow exceptions to this rule, however, and permit consideration of documents, the authenticity of which are not disputed; official public records; documents central to the plaintiffs claim; and documents sufficiently referred to in the complaint. Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993); see also Shaw, 82 F.3d at 1220 (applying the Watterson exceptions in deciding a motion to dismiss a securities action).

In the second portion of the release quoted by the plaintiffs, Gefter, the Company's CEO, discussed the Company's reaction to the FDA approval, stating:

> We are delighted with the approval, and would like to thank the FDA for diligently working with us to make this drug available for those prostate cancer patients who are most in need. The approval of Plenaxis(TM) represents years of dedication to drug discovery and development at PRAECIS to bring an innovative product to the market and marks an important milestone in our transition to a fully integrated pharmaceutical company. More importantly, this approval will bring a valuable therapy to those patients in the indicated population who have limited or no other treatment options available.

Complaint ¶ 106; Def. Ex. 1 at 1.

The third portion is a statement attributed to Heiden, the Company's COO, in which he discussed the PLUS program and the Company's plans for the Plenaxis launch:

> The launch of Plenaxis(TM) will be supported by the PLUS Program, which is designed with the goal of providing the benefits of enhanced safety for patients taking Plenaxis(TM), as well as education and support for prescribing physicians and dispensing hospital pharmacists. The PLUS Program represents an ongoing effort by the FDA and industry to identify and successfully manage the potential risks of new therapies, while ensuring that these important therapies are available to patients who will most benefit from them.
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> ***
>
> The Plus Program highlights that patient safety is our number one priority[.] . . . With this program in place, we are now able to direct this therapy into the hands of physicians to treat those patients for whom the benefits of Plenaxis(TM) outweigh the potential risks. In addition, we plan to begin working with the FDA to explore other patient populations which could be appropriately treated with Plenaxis in the future.
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> ***
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> We are extremely excited about the launch of our first product and the revenue opportunity it represents. We will begin hiring the Plenaxis(TM) sales force immediately, with initial product shipment targeted for early in the first quarter of 2004.

Complaint ¶ 107; Def. Ex. 1 at 2-3.

The plaintiffs do not appear to allege that any of these quoted portions contained affirmative misrepresentations. Rather, their claim is that the statements were misleading because of what they did not say. Specifically, the complaint alleges that the quoted statements "were each materially false and misleading when they were made because they failed to disclose and misrepresented the following adverse facts, among others, that: (i) the primary purchasers, urologists, lacked the necessary distribution system to purchase Plenaxis; (ii) Praecis' pricing structure offered the target physicians (urologists) little opportunity to profit while at the same time substantially increasing the urologists' risk of loss; (iii) the 30 minute monitoring period further decreased urologists' profits, if any, from Plenaxis because during that time a consultation room could not be used by another patient; (iv) Plenaxis' 'black box' warning label also significantly increased urologists treatment and malpractice concerns, particularly in light of the fact that the existing competing medications used to treat prostate cancer bore no such warning labels, had been effectively prescribed for fifteen years, and could be prescribed to a much larger group of prostate cancer patients." Complaint ¶ 110.

Even if the four "adverse facts" itemized by the plaintiffs are true, there are two principal reasons why the allegation that the press release was false and misleading is substantively insufficient. First, assuming that the facts are true, they must have become evident in the course of the Company's efforts to market Plenaxis, all of which necessarily followed the issuance of the press release. There is no allegation that the defendants knew those facts at the time of the press release, so that they could have known that their press release was misleadingly incomplete. In other words, there are no allegations of the necessary *scienter* with respect to these omissions.

More importantly, the four omitted "adverse facts" dealt with topics – a distribution network, physicians' profit margins, and the effect of "black box" warning labels on marketability – that were

not addressed directly in the press release. The release made no statements on those topics that needed qualification as suggested by the plaintiffs in order to avoid misleading a reader of the release. The best that can be said for the plaintiffs' position is that the omitted facts would have been of material interest to a prospective investor who would like to know as much as possible about the Company and its business. Under the case precedents, however, that is not the applicable standard of liability. See Gross, 93 F.3d at 992.

In addition, some of Heiden's statements in the release fall within the PSLRA safe harbor. His discussion of the company's plans to "explore other patient populations" with the FDA, hire a sales force, and begin initial product shipment in early 2004 were all forward-looking statements, and were accompanied by relevant and meaningful cautionary language. See 15 U.S.C. 78u-5(c); Def. Ex. 1 at 7. The news release itself contained a section addressing risks and uncertainties which highlighted "the Company's ability to hire a sales force and successfully commercialize Plenaxis(TM), [and] the Company's ability to manufacture Plenaxis(TM) on a commercial scale." as factors that might have affected Praecis' success with Plenaxis. Def. Ex. 1 at 7. The cautionary statement also referred potential investors to the Praecis SEC filings, and specifically to the risks detailed in the Company's most recent 10-Q for the quarter ended September 30, 2003. See id. That 10-Q stated:

> **Even if we receive approval for the marketing and sale of Plenaxis . . . [it] may fail to achieve market acceptance and, accordingly, may never be commercially successful.**
>
> Many factors may affect the market acceptance and commercial success for Plenaxis or any of [Praecis'] other potential products, including:
>
> - the scope of the patient population and the indications for which Plenaxis . . . [is] approved;
> - the terms of any risk management and/or controlled or managed distribution program required by the FDA in connection with the approval of Plenaxis . . .;
> - the product labeling or the product insert required by the FDA for Plenaxis. . .;

> • the effectiveness of Plenaxis . . . including any potential side effects, as compared to alternative treatment methods; . . .
> • the competitive features of our products as compared to other products, including the frequency of administration of Plenaxis as compared to other products, and doctor and patient acceptance of these features; [and]
> • the cost-effectiveness of Plenaxis . . ..

Def. Ex. 12 at 16 (emphasis in original).

While this statement obviously predates the FDA approval, it gives a fairly detailed breakdown of many of the potential risks the plaintiffs allege should have been disclosed, including those associated with FDA restrictions, such as the PLUS Program and the black box labeling; those related to doctor and patient acceptance of the drug, such as Plenaxis' cost-effectiveness, frequency of administration and side effects; and those which might limit the scope of the patient population.[9]

Finally, Heiden's statement that Praecis was "extremely excited about the launch of our first product and the revenue opportunity it represents" cannot serve as the basis for a claim of misrepresentation. Courts have routinely held such statements, generally optimistic but lacking in certainty or specifics, to be transparent "puffery," and therefore immaterial as a matter of law. See Glassman v. Computervision Corp., 90 F.3d 617, 636 (1st Cir. 1996) ("Computervision's statements did not rise to the level of optimism or certainty that would make them materially misleading in the absence of disclosure. . . [of potentially adverse facts]."); Shaw v. Digital Equip. Corp, 82 F.3d 1194, 1217-19 (1st Cir. 1996) ("In particular, courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and

[9] Even if Heiden's forward-looking statements had not been accompanied by cautionary language, they would still be protected by the PSLRA's third safe harbor provision. See 15 U.S.C. § 78u-5(c)(1)(B)(i). The plaintiffs have pled no facts that even remotely support an inference that Heiden had *actual* knowledge that his statements were false or misleading.

numbingly familiar to the marketplace-loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available. . . . [A] claim that a fraud was perpetrated on the *market* can draw no sustenance from allegations that defendants made overly-optimistic statements, if those statements are ones that any reasonable investor (ergo, the market) would easily recognize as nothing more than a kind of self-directed corporate puffery. The market is not so easily duped, even granted that individual investors sometimes are."). No claim for fraud can be supported by reference to such a general statement of corporate excitement and optimism.

B. The November 26, 2003 Conference Call and Interview

A day after Praecis received FDA approval, Company representatives made a series of oral statements regarding Plenaxis and the Company's plans for its commercialization. While participating in a conference call with investors and analysts, Marc Garnick, the Company's Chief Medical Officer, stated:

> You may have heard that the FDA has talked about five to 10 percent of all prostate cancer patients. And that's not inconsistent with some of our forecasts. As we said previously, given our market share penetrations and also our premium pricing assumptions, we've talked about a 15 percent-plus revenue opportunity of the current $1.2 billion market. And none of that has changed. That's still the case and, again, consistent with the numbers that the FDA stated, again, five to 10 percent of the total number of prostate cancer patients in the United States.

Def. Ex. 2 at 7.

Later that same day, CEO Gefter was interviewed on cable television. In response to a question about market size, he said:

> The current market for hormonal therapy is actually $1.2 billion in the United States alone. And that represents the combined hormonal therapies that are available for prostate cancer patients. And we've estimated that our drug would be applicable to treat a large segment of that population. And we have estimated somewhere north of 15 to 20 to 30 percent of that size market would be available to patients taking our drug.

Def. Ex. 3 at 2.

The plaintiffs allege that these statements were misleading because Praecis' financial forecasts "lacked a reasonable basis in fact" and because they should have been qualified by the adverse facts discussed in the previous section. As to the first ground, the plaintiffs take issue with Garnick's and Gefter's estimates that the market for Plenaxis might equal fifteen percent or more of a $1.2 billion hormonal therapy market. Complaint ¶¶ 3, 44, 45. In essence, the plaintiffs contend that the defendants must have known that such projections were false because (i) prior estimates by the American Urological Association ("AUA") and the FDA were that the patient population likely to be prescribed a drug like Plenaxis would only be between 5-10% of all prostate cancer patients and (ii) the defendants knew the FDA restrictions and distribution issues would further depress sales.

These allegations are not sufficient to state a fraud claim under the PSLRA. While it is true that the PSLRA does not require plaintiffs to "plead evidence," see In re Stone & Webster, Inc. Securities Litig., 414 F.3d 187, 199 (1st Cir. 2005), the particularity requirements of both the PSLRA and Rule 9(b) oblige plaintiffs to plead specific facts which, if presumed true, would raise a strong inference that the defendants made materially false or misleading statements with intent to deceive or with reckless disregard for the statements' veracity. Where the statements challenged by the

plaintiffs are forward-looking in nature, the PSLRA ratchets the bar even higher: the facts pled by the plaintiffs must be sufficient to raise a strong inference that the issuer of the statement had *actual knowledge* of the statement's falsity. See 15 U.S.C. § 78u-5(c)(1)(B).

Both Garnick's and Gefter's statements qualify as forward-looking; they were estimates of the "revenue opportunity" Praecis might enjoy once it began to commercialize Plenaxis. See 15 U.S.C. § 78u-5(i)(1) (defining forward-looking statements to include those "containing a projection of revenues" or statements of "future economic performance"). The facts pled by the plaintiffs do not give rise to a strong inference that either Garnick or Gefter had actual knowledge that the projections were false at the time they were made. To the contrary, a simple calculation using numbers provided by the plaintiffs suggests that the defendants could indeed have had a rational basis for their estimates. Assuming a price of $700 per dose and administration of 14 doses per year per patient, see Complaint ¶ 68, the annual charge to a patient would be $9,800. Assuming that prostate cancer affects 220,000 patients annually in the United States,[10] then the AUA and FDA estimate would be that 11,000 to 22,000 patients (5-10% of the total patient population) would be candidates for therapy such as Plenxis. The range of possible annual revenues would be between $107,800,000 ($9,800 x 11,000) and 215,600,000 ($9,800 x 22,000). A projection of 15% of a $1.2 billion market would amount to $180,000,000. This does not take into account potential future expansions of the indicated population.[11]

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[10] The November 25 press release contains this figure; the plaintiffs have not disputed it.

[11] The defendants' statements cannot fairly be understood to imply that the revenue estimates of 15% of the total hormonal therapy market were being made with respect to *first year* revenues, which were later projected to be in the range of $10-20 million. See discussion Section IV.C., infra. In fact, Gefter's statement was made in response to the interviewer's assertion that "estimates as far

The plaintiffs' contentions that Praecis' estimates were false and misleading because the Company knew of other factors that would depress sales – specifically, the low profit margin for urologists, the costs of establishing a distribution network for the drug, and the "deleterious effects" of the black box warning label and the PLUS Program – lack merit for the reasons already discussed, supra. At the time the challenged statements were made, Praecis had not yet officially set the price of Plenaxis, nor could it have known the Medicare reimbursement rate.[12] Furthermore, the plaintiffs plead no facts that would suggest that the defendants' stated estimates failed to take negative factors such as the FDA restrictions and the costs of establishing a distribution network into account.

While history ultimately proved Praecis' estimated "revenue opportunity" to be inaccurate, the plaintiffs have not provided enough specific facts to warrant a strong inference that the defendants knew the projection to be wrong at the time it was made.[13]

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as *how big this market will become* are very, very wide," see Def. Ex. 2 at 7 (emphasis added), and many of Praecis' statements regarding Plenaxis – including those made during the November 26, 2003 conference call – specifically emphasized that the Company was exploring avenues to expand the indicated patient population, both domestically and abroad. See Def. Ex. 2 at 15; see also Def. Ex. 1 at 3; Def. Ex. 4 at 2, 4.

[12]The uncertainty associated with the latter of these two factors was a risk consistently disclosed by the defendants.

[13]Garnick's statement would also be protected by the first of the PSLRA's safe harbor provisions. See 15 U.S.C. § 78u-5(c)(2) (oral statement can refer listeners to readily available written document containing risk factors). It was made during a conference call with analysts, a call that began with the following caution: "Before getting started I want to remind everyone that–about our news release and Webcast contain forward-looking statements (sic), and these statements are subject to numerous factors and uncertainties. And please refer to the factors set forth in our news release as well as the risks set forth from time to time in our filings with the SEC."

The plaintiffs argue that this warning was "legally deficient" because it did not (1) identify which statements were forward-looking; (2) specifically state that the "factors and uncertainties" could cause results to materially differ and; (3) reference *specific* documents where risks and uncertainties were detailed. See Pl. Opp. at 17-18. This argument is unpersuasive. The caution was given at the beginning of the conference call and obviously referred to statements yet to be made

C. January 30, 2004 Press Release

On January 30, 2004, Praecis issued a press release detailing its financial results for the quarter and year ended December 30, 2003. In that release, the Company through its representatives made a number of statements relating to Plenaxis and to the Company more generally which the plaintiffs allege were false and misleading:

> The past year was one of significant accomplishment for PRAECIS. In November, we achieved our primary goal for 2003 with the receipt of approval from the United States Food and Drug Administration (FDA) to market Plenaxis(TM) in the United States. This approval marks our transition to a fully integrated pharmaceutical company with capabilities spanning drug discovery, clinical development, manufacturing and commercialization. . .. We believe that the approval of Plenaxis(TM) confirms our team's ability to translate innovative scientific discoveries onto commercial reality, effectively and efficiently.
>
> ***
>
> With regard to the commercialization efforts for Plenaxis(TM), the Company has begun shipping product to distributors. Since receipt of FDA approval for Plenaxis(TM) in late November 2003, the Company has hired and trained its medical science liaisons and its regional sales managers, and is aggressively hiring and training its estimated 40 field sales representatives.
>
> ***
>
> "We are extremely pleased to announce that Plenaxis(TM) is now available through our authorized distributors to physicians and hospital pharmacies enrolled in the Plenaxis(TM) User Safety (PLUS) Program. . . . Our goal is to have 100% of our sales force hired, trained and in the field by early in the second quarter of 2004. . .."
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> ***
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> "The approval of Plenaxis(TM) is enabling us to build a commercialization infrastructure that adds tremendous value to our organization. We can leverage this infrastructure to position ourselves as a partner of choice for commercializing other urology/oncology products, advance our future products and maintain greater control

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during the call. Moreover, the analysts as an audience were undoubtedly aware of the cautionary statement's purpose and capable of discerning that the "numerous factors and uncertainties" might materially alter results. Additionally, because the conference call was held as a follow-up to the previous day's press release, the audience was able to easily identify what document Gefter meant when he repeatedly referred to "our news release."

> when evaluating partnership opportunities for our clinical stage products."
>
> The Company is continuing to evaluate the potential utility of Plenaxis(TM) in other indications to further exploit its unique mechanism of action. As part of this process, the Company has established several groups of experienced clinical advisors and continues to work closely with these groups of experts to identify indications where the use of Plenaxis (TM) may provide innovative advantages compared to existing therapies.
>
> ***
>
> The Company believes that it has adequate financial resources to achieve profitability by 2006, assuming the successful commercialization of Plenaxis(TM), the timely partnering of clinical programs and continued prudent fiscal management. During 2004, the Company forecasts sales of Plenaxis(TM) to range from $10.0 million to $20.0 million and anticipates the ramp-up of revenues to be heavily weighted toward the second half of the year. The Company anticipates updating its financial guidance throughout 2004, as it gains greater insight into Plenaxis(TM)' revenue trajectory.
>
> With respect to the future prospects for Plenaxis(TM), the market for currently available hormonal therapies to treat prostate cancer is approximately $1.2 billion in the United States. The Company believes that the long-term revenue opportunity for Plenaxis may represent 15% or more of this market.

Complaint ¶¶ 112, 113, 114; see also Def. Ex. 4.

The plaintiffs allege that these statements were false and materially misleading when made because Praecis failed to disclose a number of adverse facts, including those set forth in ¶ 110 of the Complaint, see Section IV.A, supra, as well as those specified in ¶ 115, viz. that Praecis' sales force training sessions encouraged unethical and potentially illegal sales tactics and that the Company's internal sales goals could not meet the public forecasts.

Again, the statements in the press release were accompanied by cautionary language:

> This news release contains forward-looking statements, including, but not limited to, statements regarding the Company's commercialization plans for Plenaxis(TM) . . ., the Company's expectations for sales of Plenaxis(TM) during 2004, the Company's expected cash utilization and cash position , [and] the review of a Marketing Authorisation Application in Europe for Plenaxis(TM). . . .. These statements are based on the Company's current beliefs and expectations as to future outcomes. Such statements are subject to numerous factors and uncertainties. Theses include, but are not limited to, the Company's ability to complete the hiring of its sales force and successfully commercialize Plenaxis(TM), the Company's ability to manufacture Plenaxis(TM) on a commercial scale, [and] the timing and content of decisions made by the FDA or foreign regulatory authorities.

Def. Ex. 4 at p. 7. As with prior statements, the release also referred investors to the Company's SEC filings, particularly the most recent 10-Q, filed for the quarter ending September 30, 2003.

Some of the plaintiffs' allegations about the projections have already been addressed, see Section IV. A, supra, and there is no need to repeat that discussion here. It is enough to say that the risk statement and referenced materials once again sufficiently identified factors, such as inadequate sales, that could affect the achievement of the goals outlined.

Once again, the plaintiffs have also failed adequately to plead scienter. The Complaint does not specifically allege facts that would support a conclusion that the defendants knew or recklessly disregarded the fact that their sales goals were unlikely to be achieved because, for instance, the pricing structure was flawed.[14] Absent some significant factual averment to the contrary, it is not

[14] The Complaint asserts that a confidential source formerly employed by Praecis "informed management that the pricing structure for Plenaxis was significantly flawed," although there is no allegation that this took place prior to the issuance of the January press release. Complaint ¶ 53. Assuming it to be true that the source had so "informed management," more than that would be needed to support an allegation that "management" itself knew the structure to be flawed, as opposed to knowing simply that someone else (of unclear qualifications) thought that to be the case. The

reasonable to think that the defendants intentionally launched the Company's flagship product with what they recognized was a flawed pricing structure, as if they were more interested in fooling the stock market in the short term than succeeding in the product market in the long run.

The plaintiffs' allegations about the training sessions for the sales force are a bit puzzling. The allegations are that in the training sessions members of the sales force were urged to use aggressive sales techniques, including efforts to push the "off indication" prescription of Plenaxis by physicians. Although it is never quite stated directly, it appears that the claim is that the sales force was offended by the unethical urgings of the training staff and therefore "revolted," undercutting any prospect of successful sales at the projected levels.

There is no allegation that any of the unethical training sessions had occurred prior to the issuance of the January release, so the allegations fall short of what would be necessary to support a conclusion that the training sessions tainted the statements in the release. For the same reason, no strong inference of scienter can be drawn from the allegations as to the January release.

D. The March and April 2004 Statements

Praecis released a series of statements during March and April 2004 that provided updated information on the commercialization of Plenaxis. On March 31, 2004, for example, the Company announced that Plenaxis had qualified for transitional pass-through payment under Medicare. Commenting on the approval, Praecis COO Heiden stated, "We are especially pleased to receive this news now, as initial interest in Plenaxis™ has been very encouraging, with over 1,000 physicians and

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Complaint thus deals in merely *faux* specificity. There are specific facts alleged, but those isolated facts, for all their concreteness, cannot support the broader conclusory allegations without help from other, missing facts.

hospital pharmacies having enrolled in our PLUS (Plenaxis™ User Safety) Program to date." Complaint ¶ 118.

Approximately one month later, Praecis announced its consolidated financial results for the three months ended March 31, 2004. The Company indicated that during the first quarter it had "generated net revenue of approximately $0.4 million through sales to distributors, representing primarily initial stocking levels." Commenting on the first quarter results, Gefter stated, "Although it is early in the Plenaxis™ launch, we are encouraged by the feedback from physicians and expect to build sales during the second half of the year as awareness of the product grows among urologists and oncologists." Praecis then went on to reaffirm its guidance for fiscal year 2004, stating: "Based upon the first quarter activity, the Company's prior Plenaxis™ sales forecast of $10.0 million to $20.0 million in revenue for 2004 remains unchanged." Complaint ¶¶ 120-121.

The April release also contained a summary of the quarter's commercialization activity, highlighting Praecis' efforts to build its commercial infrastructure, its establishment of a "network of premier specialty distributors," and the hiring and training of its sales force. Complaint ¶ 120. The Company then suggested that "[t]he initial impact of the Plenaxis™ sales force can be seen in the large number of physicians who have signed up to become authorized Plenaxis™ prescribers by enrolling in the PLUS Program. Currently, approximately 1,900 physicians and hospital pharmacies have enrolled." Id.

The plaintiffs have alleged that the statements made during March and April were fraudulent because Praecis failed to disclose a host of adverse facts, many of which have already been discussed. See Sections IV A, B, and C, supra. In addition, the plaintiffs claim that the Company withheld

information regarding: (1) the dismal sales in the Plenaxis launch; (2) the failure of the Plenaxis delayed payment program; (3) the failure of the Praecis' pricing structure to attract customers; (4) the significant returns of Plenaxis by physicians; (5) the anger caused by distributor "charge backs;" (6) the instructions to the sales force to "work the gray area" of indications and suggest use of the drug for patients with "mild" symptoms in order to sell Plenaxis; and (7) the "crumbling morale" of the sales force, which led to "mass" resignations and replacement by "inferior sales representatives." Complaint ¶ 122.

These additional "adverse facts" cited by the plaintiffs are not sufficient to raise a strong inference that the March and April press releases were made with intent to deceive. Heiden's statement that "initial interest in Plenaxis™ has been very encouraging" is simply an example of the "loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available." Shaw, 82 F.3d at 1217. The accuracy of the actual data he relayed regarding the number of physicians who had enrolled in the PLUS Program — a necessary prerequisite to prescribing Plenaxis — is not challenged by the plaintiffs, and the Complaint provides no hint as to whether the "significant returns" of Plenaxis, the problems with the delayed payment plan, and the anger caused by distributor charge backs were issues that had already arisen by the time Praecis released its March 31, 2004 statement. In fact, the Complaint is very unspecific about the timelines germane to any of the allegedly misleading statements. For example, because the launch of Plenaxis was just getting underway in March, see Complaint, ¶ 69, it seems unlikely that at the time of the March and April statements there had already been "significant returns" and "charge backs,"

let alone "crumbling morale" among the sales force. These things might have developed a few months later, perhaps, but it is unlikely that they happened in temporal synch with the initial rollout of the product. At the very least, it is the plaintiffs' obligation to set forth particulars that would support the general allegations they make. For example, while the plaintiffs plead that there were known flaws in the Company's pricing structure, see Complaint ¶¶ 53-56, there is no suggestion that anyone other than one "confidential source" ever expressed an opinion on the issue to Praecis management and, even with respect to that person's comment, there is no indication as to when it was made or to whom. It therefore is not possible to conclude from the facts alleged that the Company was aware of the problems with its pricing structure at the time the March and April statements were made. The plaintiffs' general allegation that Praecis failed to disclose the "dismal sales" and its inability to attract customers is clearly belied by the fact that the April statement detailed the consolidated financial results for the first quarter, including the noteworthy fact that net revenues totaled only $0.4 million.

In addition to the plaintiffs' failure to adequately plead scienter, they have also failed to demonstrate another essential element of a securities fraud claim – the materiality of the alleged omissions. Where, as here, plaintiffs assert a "fraud on the market" theory of liability, it is not appropriate to scrutinize the content of single statements in isolation; all publicly available information should be considered. The presumption is that the sophisticated, impersonal "market" has absorbed and analyzed all such information, which then is reflected in the share price of a stock. See Basic, Inc. v. Levinson, 485 U.S. 224, 246 (1988) ("[T]he market price of shares traded on well-developed markets reflects all publicly available information."). A fact is "material" only if it is "substantially likely 'that the disclosure of the omitted fact would have been viewed by the reasonable investor as

having significantly altered the total mix of information made available.'" In re Cabletron Sys., Inc., 311 F.3d 11, 34 (1st Cir. 2002) (quoting Basic, 485 U.S. at 231-32) (internal quotations omitted).

Here, the Company's 10-K, which was filed with the SEC on March 15, 2004, contained the following statements:

> [O]ur actual revenues will depend upon the impact of our risk management program, physician and patient acceptance of Plenaxis and the overall success of our commercialization efforts. . . .
>
> **We have a history of losses and anticipate significant increases in our operating expenses over the next several years, and we may not be profitable in the future. . . .Our business is dependent on the commercial success of Plenaxis. If Plenaxis fails to achieve market acceptance, it may never be commercially successful and we may be unable to continue our operations as planned.** . . . Plenaxis is new to the market and may be unfamiliar to members of the medical community and to patients. Market acceptance will depend largely on our ability to demonstrate, to the oncology and urology communities in particular, the efficacy and safety of Plenaxis as an alternative to currently marketed therapies or surgical options. We cannot be certain that Plenaxis will provide benefits considered adequate by providers of oncology and urology services or that enough providers will use the product to ensure its commercial success.
>
> Def. Ex. 13 at 24, 31-2 (emphasis in original).

The 10-K then goes on to highlight many of the risks the plaintiffs allege were not disclosed, including the limited scope of the patient population and the indication for which Plenaxis was approved; the terms of the risk management program imposed by the FDA, including the product labeling (the "black box") and insert required; the side effects of Plenaxis, including the risk of immediate-onset systemic allergic reactions; questions regarding the cost-effectiveness of Plenaxis for prescribers; and how "burdensome" physicians might view these various factors to be. See id. at 32-3. Finally, the Company highlighted the importance of its sales force to the successful commercialization of Plenaxis, stating: "Recruiting and retaining qualified sales personnel is . . .

critical to our success . . . . and we cannot assure you that we will be able to attract and retain a sufficient number of qualified individuals to successfully launch Plenaxis." Id. at 32.

These statements from the Praecis 10-K indicate that the market was in fact on notice that Praecis' financial future hinged on the successful commercialization of Plenaxis, and that the commercialization process itself might be hampered by many of the same adverse factors the plaintiffs allege were not disclosed by the Company. From at least March 15, 2004 forward, then, the share price of Praecis stock should be presumed to have accurately reflected all of this publicly available information, including the Company's ongoing disclosure of its poor revenue numbers.[15]

E. The May 2004 Statement

On May 24, 2004, Praecis provided an update on the commercialization of Plenaxis. Once again, the gist of the plaintiffs' complaint does not seem to be that the information actually contained in the news release was false,[16] but rather that the release was misleadingly optimistic due to the Company's failure to mention the adverse facts discussed previously, particularly the "illegal and unethical" attempts to downplay the risks of Plenaxis and expand the class of patients to whom it could be prescribed, and the "substantial attrition" of the trained sales force. Complaint ¶ 125. The

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[15]Because there is no indication in the Complaint that any of these risks had actually materialized by the time the challenged statements were made, the defendants' detailed statement of the potential risks that might have an adverse effect on Plenaxis commercialization was more than sufficient at that point. The plaintiffs' citations to cases such as Huddleston v. Herman & MacLean, 640 F.2d 534, 544 (5th Cir. 1981) and Mayer v. Mylod, 988 F.2d 635, 639 (6th Cir. 1993), which suggest that general statements of potential risks which conceal existing problems are actionable, therefore are inapposite.

[16]The majority of the statements highlighted by the plaintiffs recite historical facts about the Plenaxis commercialization process that the plaintiffs do not allege were literally untrue. See Complaint ¶ 124.

argument that the release was somehow unrealistically and deceptively positive or optimistic due to these omissions is specious. Significantly, the plaintiffs fail to mention that it was in the May 24th release that Praecis first publicized the fact that it was not in a position to confirm its previously issued sales forecast for 2004, stating:

> [T]he uptake of the product by prescribers during the initial sixteen weeks has been somewhat slower than forecasted. Accordingly, the Company is not in a position at this time to confirm its previously issued sales range forecast for 2004. The Company cannot predict at this time what effect, if any, this could have on its longer-term capital position and previously disclosed expected timing for reaching profitability, but does not currently anticipate that it would be material.

Def. Ex. 8 at 2-3.

Coming as it did on the heels of the Company's 10-Q for the first quarter of 2004 – which disclosed net revenues of only $400,000 and an operating loss of over $15 million – it is difficult to see how the May 24, 2004 release, considered in its entirety, could have deceived the marketplace into thinking that the Plenaxis launch had gone well and/or that the Company's outlook for 2004 was promising. In light of the detailed negative financial information actually disclosed, the Company's omission of details regarding difficulties with its sales force or marketing message would not have "significantly altered the total mix of information made available." In re Cabletron Sys., Inc., 311 F.3d 11, 34 (1st Cir. 2002) (quoting Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)) (internal citations and quotations omitted). The sales and marketing difficulties were apparent in the reported results.

Lastly, in addition to the plaintiffs' failure to adequately plead materiality, their allegations with respect to the May 2004 press release fall short of supporting a strong inference that the

defendants acted with culpable scienter when issuing the release. As with many of the plaintiffs' previous allegations, the flaw is simple, but significant: in the few instances where the plaintiffs plead facts sufficient to establish *what* information the defendants might have known, they fail to establish a crucial factor, namely *when* the defendants knew that information. For example, even if information about sales force morale and the promotion of off-label sales would have been material at the time the May 24, 2004 statement was made, as noted above, see Section IV. D, the Complaint itself suggests that it was not until the second half of 2004 that the majority of the experienced sales representatives were alleged to have left the Company. See Complaint ¶ 6. Of the seven sales representatives who served as "confidential sources" to plaintiffs, only two *might* have been gone by the time the May 24, 2004 statement was released; they are described as having worked at the Company until "mid 2004," whatever that means. Id. ¶¶ 30, 32. The remainder apparently did not leave until late 2004 or later. See id. ¶¶ 28-34. Similarly, the Complaint indicates that it was *after* and "[d]espite the Company's May 24, 2004 statement that it would no longer confirm its sales forecasts" that Praecis really began pressuring its sales force to switch to an off-indication sales message, specifically at a meeting held in June, 2004. Id. ¶¶ 81-90.

F. The July 30, 2004 Press Release and August 10-Q

Praecis announced its consolidated financial results for the first two quarters on July 30, 2004, and reconfirmed them in the 10-Q it filed with the SEC ten days later. As part of its announcement, the Company stated that the Plenaxis commercialization process had included the "build-up" of a field sales force of about 40 individuals and led to the enrollment of approximately 3,000 potential prescribers in the PLUS Program. Complaint ¶ 127. The release further stated that 10% of those enrolled in the PLUS Program had actually purchased Plenaxis and indicated that the Company had

begun to shift its focus away from "educating new physicians and enrolling then in the PLUS Program" and toward encouraging PLUS-enrolled physicians to "take the next step and become Plenaxis(R) prescribers. Id. Praecis' COO Heiden also commented that the Company had achieved some success with this strategy, having observed a "trend of increasing weekly sales which began in the latter portion of the second quarter" and suggested that the Company "expect[ed] to see Plenaxis(R) sales continue to build quarter on quarter over the course of the year." Id. Finally, the Praecis reiterated its belief that "[l]onger-term . . .the revenue opportunity for Plenaxis may represent 15% or more of the 1.2 billion hormone therapy market for prostate cancer in the United States." Id.

The plaintiffs allege that these statements were false and misleading but fail to specify at all why that might be so. See Complaint ¶ 130. Absent any citation to particular facts that would support a claim that the statements in the press release and 10-Q were false and misleading, the plaintiffs clearly have not met the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b).

G. The October 29, 2004 Press Release

The final set of statements alleged to be false and misleading were contained in Praecis' October 29, 2004 news release. In the release, the Company announced its financial results for the three and nine months ending September 30, 2004. Praecis stated that it had generated approximately $1,032,000 in revenues from Plenaxis during the third quarter and highlighted the following facts: (1) that the Company had enrolled over 3,400 physicians and pharmacists in the PLUS Program; (2) that 15% of enrollees had actually purchased Plenaxis (as opposed to 10% at the close of the second

quarter); and (3) that approximately half of the physicians who had purchased Plenaxis had already become repeat prescribers. Def. Ex. 11

Commenting on these trends, Kevin McLaughlin, the Company's recently-appointed President and COO, stated:

> We are encouraged by the growing base of sales to repeat prescribers. This trend suggests that following their first experience with Plenaxis ®, physicians are pleased with the results and thus are continuing to treat existing patients with, and identify new patients for, Plenaxis® therapy. Accordingly, we expect to see Plenaxis® sales continue to build quarter on quarter. We recognize that our sales and marketing organization has faced many challenges, both expected and unexpected, in introducing Plenaxis® to the marketplace. These challenges include the need to clearly differentiate, and educate physicians on, the indicated patient population. We believe our ability to meet these challenges has been substantially enhanced by our recently announced hiring of Michael J. Keavany as Senior Vice President, Sales and Marketing, to lead the Plenaxis® commercialization efforts. Mr. Keavany's strong background in marketing specialty products will be invaluable towards meeting our commitment of making Plenaxis® a commercial success.

Complaint ¶ 132. The statements contained in the release also made it clear that Praecis' experience with Plenaxis over the first three quarters of 2004 had led to a significant shake up in the Company's senior management, with the appointment of, at a minimum, a new president and COO and a new vice president of sales and marketing.

The plaintiffs contend that Praecis' October press release was false and misleading because the Company failed to disclose a number of adverse facts, including the failure of the drug's pricing structure and the delayed payment plan; sales force attrition; and significant returns of Plenaxis by physicians. Given the poor financial results reported by Praecis and the replacement of key members of the Company's senior management team, the disclosure of the other adverse facts cited by the

plaintiffs would not have significantly altered the total mix of information available to the market. For example, while information about returns of Plenaxis might have been incrementally useful to investors evaluating Praecis' hopeful claims about repeat prescribers, the overall status of the Company and its success (or lack thereof) with Plenaxis was glaringly apparent from the news release: revenues had increased by less than half a million dollars; the Company had managed to get only 15% of PLUS Program enrollees to actually prescribe the drug, a marginal increase over the previous two quarters; and the Company, which had months before indicated its inability to confirm its 2004 revenue projections, was openly acknowledging that it had faced "many challenges, both expected and unexpected" that had hindered its commercialization of Plenaxis.

As the discussion above demonstrates, the plaintiffs must show more than just the defendants' failure to disclose potentially adverse facts, as "nondisclosure does not by itself establish materiality." In re Parametric Tech. Corp., 300 F. Supp. 2d 206, 215 (D. Mass. 2001). They must, at a minimum, articulate facts that show how the omitted information would have significantly altered the total mix of information available to the market. The plaintiffs have not done so with respect to the October press release, and thus have failed to plead the element of materiality with sufficient particularity.

Similar deficiencies exist with respect to the plaintiffs' scienter allegations. They have not provided any indication that the adverse facts were intentionally omitted from the press release, nor pled facts that would make it appear more probable than not that the omission was for the purpose of deceiving, manipulating or defrauding the market.

H. Summary

The plaintiffs' allegations are sufficient to support the proposition that the defendants were unable successfully to launch Plenaxis as an attractive product and to achieve the goals they had set for their business. It may be that the task was more difficult than they conceived it would be. It may be they were simply poor business strategists. What the allegations do not support is the proposition that the defendants knowingly and intentionally misled the market about the trajectory of Praecis' business. The Company's forecasts were perhaps unduly optimistic. But when they did not pan out as expected over the year, that fact was disclosed in varying ways -- including detailed (and apparently accurate) reports of actual results, withdrawal of "guidance," and later a shakeup of upper management. The market's optimism gradually waned and ultimately collapsed, in parallel with these disclosures but that happened because it knew the truth, not because it was fooled.

V. Analysis of the Section 20(a) Claims Against the Individual Defendants

The second count of the plaintiffs' complaint alleges that Individual Defendants Gefter, Heiden, McLaughlin and English violated of Section 20(a) of the Exchange Act, which permits plaintiffs to assert a cause of action against any individual who exerts either direct or indirect control over a corporation that has violated federal securities laws. See 15 U.S.C. § 78t(a). As the statute makes clear, the predicate for a viable Section 20(a) claim is a company's violation of the securities laws. Thus, because the plaintiffs have failed to sufficiently plead their 10(b) claim, they cannot sustain their claims against the Individual Defendants, regardless of the degree of control over those individuals may have had over the Company and its commercialization of Plenaxis.

VII. Conclusion

For the foregoing reasons, the motion to dismiss the consolidated amended complaint (Dkt. No. 26) filed by Praecis Pharmaceuticals and the Individual Defendants is GRANTED and the complaint is accordingly DISMISSED..

It is SO ORDERED.

March 28, 2007
DATE

/s/ George A. O'Toole, Jr.
DISTRICT JUDGE